UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA PHARMACEUTICAL INDUSTRIES LTD. and TEVA PHARMACEUTICALS USA, INC.,	:	Civil Action No.: 2:08-cv-3706 (DMC)
	:	Related to C.A. No. 02-3779
Plaintiffs,	:	
v.	:	
SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE,	:	
Defendant.	:	

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANT'S MOTION FOR JUDGMENT ON THE PLEADINGS

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INTRODUCTION

Defendant SmithKlineBeecham Corporation d/b/a GlaxoSmithKline's "("GSK") Motion for Judgment on the Pleadings is a cynical attempt to rewrite the License and Supply Agreement among the parties ("License Agreement") to deprive Plaintiffs Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. (collectively, "Teva") of the key consideration Teva bargained for in that contract. In its motion, GSK misreads the License Agreement in a way that would nullify key provisions, claiming that a single sentence, intended to provide clarification, swallows up the entirety of the provision it purports to clarify. GSK's interpretation, in addition to ignoring the very provision on which it purports to rely, makes no attempt to read the provision or the License Agreement as a whole, or to harmonize its various parts. GSK's reading of the License Agreement is inconsistent with applicable Pennsylvania law and the intent of the parties and therefore must be rejected.

As the Complaint alleges, the License Agreement granted Teva an exclusive right—including as to GSK and its affiliates—to sell generic lamotrigine, a treatment for epilepsy and bipolar disorder. GSK was free to continue selling its product as a brand, and to compete with Teva's product through price reductions in its product. But GSK promised in the License Agreement not to sell its product as a generic during the brief period of Teva's exclusivity. GSK plainly breached its promises in the License Agreement by arranging for customers to dispense its branded lamotrigine tablets (sold under the brand name Lamictal®) "as the generic," to use GSK's own words. The sole purpose for this odd arrangement that GSK concocted was to prevent Teva from successfully launching the very generic lamotrigine product that the License Agreement authorized and contemplated would be Teva's exclusive prerogative. In other words, even though GSK promised that it would not sell generic lamotrigine, it did precisely that, and it did so in a way intended to ensure that the launch of Teva's generic lamotrigine would not

succeed. GSK not only breached the express language of the License Agreement, but it acted in manifest bad faith in doing so.

GSK seeks to evade its obligations under the License Agreement by latching on to a single sentence at the end of the definition of the term "Generic Equivalent" which, by its plain language, was added only to avoid doubt and not to substantively restrict the definition of the term. This sentence, which GSK drafted, merely clarifies that Teva's exclusive right to sell generic lamotrigine is not intended to diminish GSK's ability to sell Lamictal® as it had been selling it previously. It does not, as GSK argues, authorize GSK to sell Lamictal® "as a generic," as GSK has done here. It certainly does not authorize GSK to attempt to thwart Teva's launch of generic lamotrigine by compelling customers to dispense Lamictal® as generic lamotrigine. GSK's reading of the License Agreement would impermissibly read out of that contract both its core purpose and the provisions relating to Teva's exclusive rights.

Even if the License Agreement could somehow make sense under GSK's interpretation, the final sentence of the "Generic Equivalent" definition on which GSK relies is nonetheless plainly ambiguous and cannot be interpreted as GSK suggests on this motion. Since GSK itself drafted the sentence on which it now seeks to rely, Teva should be entitled—at the appropriate time—to offer parol evidence to show that GSK's interpretation of the License Agreement is neither what the parties intended nor acceptable under Pennsylvania law.

BACKGROUND

The Patent Lawsuit Between GSK and Teva

This dispute arises from a settlement agreement between GSK and Teva that resolved patent litigation between them concerning the drug lamotrigine, which GSK has marketed under the brand name Lamictal®. Complaint ("Compl.") ¶ 2. Until this year, GSK was the sole supplier of lamotrigine as a result of certain patent rights it claimed.

In 2002, Teva filed an Abbreviated New Drug Application ("ANDA") with the FDA for approval to market a generic product equivalent to GSK's Lamictal® tablets. GSK responded by suing Teva for patent infringement. Compl. ¶¶ 14, 17. Teva replied by, among other things, challenging the validity of GSK's patent as to lamotrigine.

At the conclusion of the bench trial of the matter, this Court (Bissell, J.) denied GSK's motion for judgment as a matter of law and informed counsel in open court that it planned to find in favor of Teva with respect to at least one of GSK's patent claims. Compl. ¶ 19. The Court did not, however, indicate how it intended to rule on the other patent claims at issue in the lawsuit. The outcome therefore was in substantial doubt. This induced the parties to enter into a settlement, which is memorialized in several documents, including the Settlement Agreement and the License Agreement, both dated February 16, 2005. Compl. ¶ 20. On April 4, 2005, the parties submitted a Stipulation and Order of Dismissal in the Patent Litigation which dismissed all claims and counterclaims in the litigation. Compl. ¶ 21.

The License Agreement

The compromise settlement of the lawsuit provides certain benefits to both parties. Compl. ¶ 20. The License Agreement permitted GSK to maintain its status as the sole seller of lamotrigine products in the U.S. for a certain period of time (though for a shorter period than if GSK ultimately had prevailed in the lawsuit). In addition, the License Agreement permitted Teva to start selling its generic lamotrigrine earlier than Teva could have if the lawsuit had continued and GSK had prevailed. The License Agreement grants to Teva a right to sell generic lamotrigine for a six-month period when it otherwise would have been prohibited from doing so, and the parties made clear that this right was *exclusive*—including as to GSK and its affiliates. Compl. ¶¶ 21-22. Sections 2.3(a) and (b) of the License Agreement provide that:

> GSK hereby grants Teva (and its Affiliates) an ***exclusive (even as to GSK and its Affiliates and Third Parties with respect to Generic Equivalents)*** non-transferable (or otherwise non-assignable or non-sublicensable) waiver, with respect to [Teva's ANDA filings] any Pediatric Exclusivity granted for Lamotrigine to GSK (or its Affiliate).

License Agreement at § 2.3(b) (emphasis added).[1]

That the grant would be exclusive even as to GSK was critical here, because the benefit conferred to Teva from this License Agreement was of such a short duration. GSK's pediatric exclusivity under its patent was to expire on January 22, 2009. Compl. ¶ 16. The License Agreement authorized Teva to launch its lamotrigine product at the close of business on July 21, 2008. Thus, the benefit to Teva of the License Agreement was a brief, six-month window in which it would be the first and only supplier of generic lamotrigine. Compl. ¶ 21.

The definition of "Generic Equivalent" was intended to ensure that GSK itself did not sell its product as a generic for the brief duration of the exclusive grant to Teva. "Generic Equivalent" is defined in Section 1.1 of the License Agreement to mean:

> on a product by product basis, any (i) FDA approved (for the avoidance of doubt, not a tentative approval) prescription generic Lamotrigine tablet product (in either 25mg, 100mg, 150mg or 200mg strength, as the case may be) for human use that is A Rated to, ***or supplied or manufactured by or for GSK (or its Affiliates) under NDA No. 20-241 for sale in the Territory as a generic equivalent to, the applicable 25mg, 100mg, 150mg, or 200mg strength of GSK's Lamictal® (Lamotrigine) tablets approved under GSK's NDA No. 20-241***. . . . For the avoidance of doubt, Generic Equivalent shall not include any Product sold under GSK's Lamictal® or Lamictal XR trademark, or other trademarks owned or controlled by GSK (or its affiliates).

License Agreement at § 1.1 (emphasis added).

[1] A copy of the License Agreement is attached as Exhibit B to GSK's Answer (Docket Item ("D.I.") 11).

Included within this definition is language aimed at prohibiting GSK from marketing an "authorized generic." At the time this language was drafted, a pharmaceutical company such as GSK that marketed a brand-name drug under an NDA would sometimes introduce—either by itself or through an affiliate—an authorized generic just before the first third-party generic came to market. *See Mylan Pharma. v. United States Food and Drug Admin.*, 454 F.3d 270, 273 (4th Cir. 2006). An authorized generic is marketed under the NDA for the original brand-name drug, instead of another company's ANDA. The purposes for marketing an authorized generic include (1) lowering the market share captured by the third-party generic company and (2) recouping some of the profits lost through the steep decline in sales of the original brand-name drug upon generic entry. *Id.* Authorized generics are plainly prohibited by the License Agreement because the definition of "Generic Equivalent" includes product that is "supplied or manufactured by or for GSK (or its Affiliates) . . . as a generic equivalent to . . . GSK's Lamictal® (Lamotrigine) tablets. . . ." License Agreement at § 1.1. That is, the parties specifically considered the possibility that GSK might want to sell an authorized generic or otherwise sell something that is a "generic equivalent" to Lamictal® during Teva's six-month exclusive period, but agreed that GSK would not be permitted to do so.

The final sentence of the "Generic Equivalent" definition—inserted by GSK during negotiations—clarified that although GSK was sacrificing the ability to sell its NDA product as a generic (whether as an authorized generic or otherwise), the parties did not intend that GSK could not continue to sell Lamictal® as it had before.

GSK's Breach of the Agreement

Several years after having bound itself to an exclusive license to Teva to sell generic lamotrigine, GSK set out to thwart Teva's exclusive rights just as Teva was preparing to launch

its generic lamotrigine product. Compl. ¶ 24, 28. It struck upon an ingenious plan to attempt to crowd Teva out of the generic market. GSK approached various customers—pharmacies, large pharmacy chains, group purchasing organizations, and long-term care facilities—and proposed that they purchase GSK's Lamictal® to be sold as generic products to consumers. Compl. ¶ 25. GSK expressly directed in its written proposals that the customers were to "dispense GSK Product(s) *as the generic* during the Term of the Agreement" (emphasis added). *Id.*

The way GSK arranged for customers to do this was by prescribing Lamictal® under a "DAW5" code. Compl. ¶ 26. DAW codes are "dispense as written" codes that inform a pharmacy what kind of product to dispense and, increasingly, that dictate what kind of reimbursement the pharmacy may receive from managed care organizations and state Medicaid programs. *Id.* Such programs often prohibit pharmacies from prescribing branded products where a generic is available in order to contain costs. "DAW5" is a code that signifies that a branded product is permissibly being dispensed *as a generic*. *Id.* If a pharmacy uses the DAW5 code, it will be reimbursed the amount usually reimbursed for the generic, even though it actually dispensed a branded product. *Id.* In other words, DAW5 exists to permit pharmacies to dispense a branded product *as the generic* under certain specific circumstances, and be reimbursed as if it had dispensed a generic product.

GSK's proposal to its customers was that they dispense Lamictal® under a DAW5 code, and thus accept the lower generic product reimbursement rate for the product. Compl. ¶ 26. GSK promised to make the pharmacies whole for the losses that such a practice would cause by giving discounts on various products GSK offered. GSK's scheme, in essence, was to offer Lamictal® as a generic product and to cause customers to treat it in all respects as a generic

product. GSK's proposal to customers expressly recognizes that it is selling its branded products "as the generic."

The timing of GSK's efforts demonstrates its bad faith and intent to cause injury to Teva by depriving Teva of the benefits of the License Agreement. GSK made its proposal to customers immediately prior to Teva's agreed upon launch date for generic lamotrigine. Compl. ¶ 24, 28. Thus, although it had been selling Lamictal® for years, it chose the moment before Teva's lamotrigine launch to announce this unusual scheme. This was not, as GSK now suggests, a mere discount program or sales pitch. GSK could have discounted branded Lamictal® without requiring that it be dispensed as a generic. Rather, GSK's conduct was a concentrated, purposeful attempt to prevent Teva's generic from obtaining market penetration by supplying generic lamotrigine to customers—precisely what the License Agreement forbids.

ARGUMENT

I. THE STANDARD FOR DECIDING A MOTION FOR JUDGMENT ON THE PLEADINGS.

When, as here, a defendant asserts in a Rule 12(c) motion that the plaintiff has failed to state a claim on which relief can be granted, the standard applied by the court in deciding the motion is the same as for a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6). *Turbe v. Gov't of the Virgin Islands*, 938 F.2d 427, 428 (3d Cir. 1991). Thus, the court must accept all factual allegations in the complaint as true and must view them in the light most favorable to plaintiff. *Phillips v. County of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008). All contravening assertions in defendant's pleadings are taken to be false. *Daley v. Haddonfield Lumber Inc.*, 943 F. Supp. 464, 466 (D.N.J. 1996). The motion must be denied unless the defendant clearly establishes that no material issues of fact remains to be resolved and that defendant is entitled to judgment as a matter of law. *Soc'y Hill Civic Ass'n v. Harris*, 632 F.2d 1045, 1054 (3d Cir.

1980) (internal citation omitted). As discussed below, GSK wholly fails to meet this stringent standard.

II. TEVA HAS AMPLY PLED THAT GSK BREACHED THE LICENSE AGREEMENT BY SELLING LAMICTAL® AS A GENERIC.

A. The License Agreement Unambiguously Prohibits GSK From Marketing Any Lamotrigine Product as a Generic.

The language of the License Agreement, in furtherance of its obvious purpose, grants Teva an exclusive right to sell generic lamotrigine and prevents GSK from doing precisely what it did here—selling generic lamotrigine. Although GSK focuses its argument entirely on the last sentence of the definition of "Generic Equivalent," when that provision and the License Agreement are read as a whole as they must be,[2] GSK's argument is palpably untenable.

As noted above, Sections 2.3(a) and (b) of the License Agreement grant Teva "an exclusive (even as to GSK and its Affiliates and Third Parties with respect to Generic Equivalents)" right to sell generic lamotrigine. License Agreement at § 2.3(b). "Generic Equivalent" is specifically defined to include any FDA approved "prescription generic Lamotrigine tablet product" that is "A Rated to, or supplied or manufactured by or for GSK (or its Affiliates) under NDA No. 20-241 for sale in the Territory as a generic equivalent to . . . GSK's Lamictal® (Lamotrigine) tablets approved under GSK's NDA No. 20-241." *Id*. at § 1.1. Thus, if lamotrigine is manufactured or supplied by GSK, and it is offered for sale as a "generic equivalent"—lower case—to Lamictal®, it is a "Generic Equivalent," and GSK cannot market or sell it.[3]

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[2] "[I]n ascertaining [the parties'] intention effect must be given to all the provisions of the contract." *Felte v. White*, 451 Pa. 137, 143, 302 A.2d 347, 351 (1973). The courts "will not consider merely individual terms utilized in the . . . contract, but the entire . . . provision to ascertain the intent of the parties." *401 Fourth Street, Inc. v. Investors Ins. Group*, 583 Pa. 445, 455, 879 A.2d 166, 171 (2005).

[3] GSK's argument regarding the distinction between "generic equivalent" (lowercase) and

This provision, which GSK's argument simply ignores, unambiguously highlights the intent of the parties at the time they entered into the License Agreement to grant Teva exclusivity, even as to GSK, with respect to generic lamotrigine for a brief six-month period. This language, which is the heart of the "Generic Equivalent" definition, clearly prohibits GSK from marketing an "authorized generic" or otherwise selling something that is a "generic equivalent" to Lamictal®. As explained above, at the time the parties entered into the License Agreement, pharmaceutical companies such as GSK facing expiry of patent-derived exclusivity for a brand-named drug would sometimes market—either by themselves or through an affiliate—an authorized generic under their own NDAs just before entry of the first third-party generic. *See Mylan*, 454 F.3d at 273.[4] The parties clearly contemplated the possibility that GSK might want to sell generic lamotrigine and they chose to prohibit it. Indeed, that the definition of "Generic Equivalent" is broader than a mere proscription against authorized generics—in fact, they did not use the term "authorized generic" at all but used more general language—underscores the parties' broad shared intent to preclude any means by which GSK might sell lamotrigine to the generic market, whether as an authorized generic or otherwise.[5]

"Generic Equivalent," GSK's Br. (D.I. 27) at 3, 9 n. 5, lacks merit. The definition of "Generic Equivalent" expressly uses the term "generic equivalent" (lowercase). GSK's attempt to suggest that those easily understood, common words somehow should not be understood in their ordinary sense is utterly without support in the License Agreement or Pennsylvania law. Even if accepted, this argument would simply suggest an ambiguity in the language of the License Agreement that would preclude judgment on the pleadings. *See infra*, § II(D).

[4] It is appropriate to consider industry practices when construing a contract which, as here, contains ambiguous terms. *See Mellon Bank, N.A. v. Aetna Bus. Credit, Inc.*, 619 F.2d 1001, 1011 (3d Cir. 1980).

[5] "The fundamental rule in interpreting the meaning of a contract is to ascertain and give effect to the intent of the contracting parties." *Murphy v. Duquesne Univ.*, 565 Pa. 571, 591, 777 A.2d 418, 429 (Pa. 2001). Here, the clear intent of the language of "Generic Equivalent" was to ensure that the exclusive grant to Teva was not interfered with by an attempt by GSK to sell lamotrigine as a generic product.

The portion of the "Generic Equivalent" definition that GSK ignores makes perfectly clear that GSK cannot sell generic lamotrigine during the period of its exclusive grant to Teva. That the parties would agree on this is perfectly sensible given the short duration of Teva's exclusive rights and given the known industry practice under which pharmaceutical companies sometimes launched generics of their own branded products.

B. The Final Sentence of the Definition of "Generic Equivalents" Cannot be Interpreted as GSK Proposes.

While ignoring the critical provision cited above, GSK contends that the final sentence of the "Generic Equivalent" definition permits it to sell its Lamictal® lamotrigine tablets in any manner its sees fit without breaching the License Agreement. GSK's reading, however, is illogical and violates basic principles of contract construction under Pennsylvania law.

The sentence on which GSK's entire argument is premised reads: "For the avoidance of doubt, Generic Equivalent shall not include any Product sold under GSK's Lamictal® or Lamictal XR trademark, or other trademarks owned or controlled by GSK (or its affiliates)." As a threshold matter, this sentence, by its express terms, is intended only for "avoidance of doubt" and thus cannot controvert other language in the contract that clearly prohibits GSK from marketing any lamotrigine product as a generic for the limited period at issue.[6] Whatever the final sentence of the definition of "Generic Equivalent" may mean, it is clear that the parties did not intend that sentence to create new rights or obligations, but merely to clarify those stated elsewhere in the License Agreement. GSK thus overreaches when it construes the final sentence as granting it substantive rights found nowhere else in the License Agreement; indeed, it cites to no other provision as a justification for its construction.

[6] *See Ludwig Honold Mfg. Co. v. Fletcher*, 405 F.2d 1123, 1131 (3d Cir. 1969) ("Minor provisions must be construed as not to conflict with the main purpose of the contract.").

More importantly, GSK's reading of the final sentence of the definition of "Generic Equivalents" would render the rest of that provision a nullity. If the final sentence means that that GSK could sell Lamictal® "as a generic"—as it indisputably did—then the remainder of the definition would cease to have meaning.[7] By binding itself not to supply or manufacture product that is a generic equivalent to lamotrigine, GSK would have given up nothing if it could simply sell any generic product it wanted by calling it Lamictal®. Under GSK's misreading of the "Generic Equivalent" definition, the final sentence would swallow up the whole, by giving GSK an easy manner in which to render the entire restriction—the guts of the License Agreement—meaningless.

GSK's reading would not only do violence to the definition of "Generic Equivalent," but would undermine the exclusive right on which the entire License Agreement was premised. Sections 2.3(a) and (b) are crystal clear that the rights granted to Teva are exclusive "even as to GSK and its Affiliates and Third Parties with respect to Generic Equivalents." If GSK were permitted to sell into the generic market whatever lamotrigine it wished, simply by labeling it Lamictal®, this would become a hollow promise.[8] The Court should reject such an interpretation as commercially unreasonable.[9]

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[7] "Pennsylvania courts long have admonished that contract terms will not be construed in such a manner so as to render them meaningless. . . ." *USX Corp. v. Liberty Mut. Ins. Co.*, 444 F.3d 192 (3d Cir.) (internal citation omitted); *Capek v. Devito*, 564 Pa. 267, 274, 767 A.2d 1047, 1050 (Pa. 2001) ("An interpretation will not be given to one part of the contract which will annul another part of it.") (quoting *Cerceo v. DeMarco*, 391 Pa. 157, 162, 137 A.2d 296, 298 (1958)).

[8] *See Philip Morris Inc. v. Pittsburgh Penguins, Inc.*, 589 F. Supp. 912, 917 (W.D. Pa. 1983), *aff'd*, 738 F.2d 424 (3d Cir. 1984) ("When considering two parts of a contract, the court must not interpret the sections in such a way that the meanings will be altered. The two parts must be read together and harmonized if possible.") (internal citation omitted); *Keystone Fabric Laminates, Inc. v. Federal Ins. Co.*, 407 F.2d 1353, 1356 (3d Cir. 1969) ("It is axiomatic in contract law that two provisions of a contract should be read so as not to be in conflict with each other if it is reasonably possible.").

[9] *See Glenn Distribs. Corp. v. Carlisle Plastics, Inc.*, 297 F.3d 294, 301 n.4 (3d Cir. 2002)

When read in context with the rest of the License Agreement, including the exclusive grant provided in Sections 2.3(a) and 2.3(b) and the inclusion of all forms of generic equivalents in the definition of the term "Generic Equivalent," the meaning of the last sentence in that definition is clear. This last sentence—inserted by GSK during negotiations—clarifies that although GSK was sacrificing the ability to market any lamotrigine product as a generic, the parties agreed that GSK could continue to sell its branded Lamictal® tablets as it had before, as a brand.[10] The final sentence of the "Generic Equivalent" definition in no way justifies GSK's misconduct.[11]

(holding that the courts must "adopt an interpretation . . . which under all circumstances ascribes the most reasonable, probable, and natural conduct of the parties, bearing in mind the objects manifestly to be accomplished") (quoting *Metzger v. Clifford Realty Corp.*, 327 Pa. Super. 377, 385, 476 A.2d 1, 4 (1984)).

[10] This proper interpretation of the last sentence in the definition also explains why, contrary to GSK's argument, GSK's Br. (D.I. 27) at 9 n.6, Lamictal® marketed as generic can be a "Generic Equivalent" without the definition being circular. The reference in the definition is not simply Lamictal® lamotrigine tablets in general, but such tablets as they were marketed at the time the parties entered into the contract, *i.e.*, marketed in the typical manner that brand-name drugs are marketed.

[11] GSK's attempt to suggest that its interpretation of the License Agreement is somehow pro-competitive, and that Teva's is anti-competitive, is backwards. The License Agreement is plainly procompetitive by permitting early entry of Teva into the generic market and vastly expanded consumer choice with respect to lamotrigine. At the time the parties entered into the License Agreement, the *only* lamotrigine product on the market was GSK's Lamictal® lamotrigine tablets, as to which GSK enjoyed a patent-derived exclusivity. The intent of the parties was to introduce generic competition ending GSK's exclusivity and for Teva to be the sole generic supplier for a brief duration. GSK's conduct in this case, however, far from being pro-competitive, has simply complicated Teva's launch of lamotrigine and entrenched GSK's own exclusive position. Moreover, GSK's implicit suggestion that Teva's interpretation would lead to higher prices is patently absurd. As GSK concedes, it is free under the License Agreement to discount the price of Lamictal® as deeply as it chooses to compete with Teva, so long as it continues to sell Lamictal® as a brand. This dispute, therefore, has nothing to do with price; it has everything to do with the channel through which product is sold, brand or generic. In any event, GSK is not simply discounting Lamictal® but is merely attempting to induce customers not to buy Teva's generic product with promises that GSK will make the customers whole by discounts on various GSK products. It is GSK who has acted to thwart competition here.

C. It Is Indisputable That GSK Breached the License Agreement, as Properly Construed.

There can be no reasonable dispute that GSK breached the License Agreement, as properly construed, by marketing and selling its Lamictal® lamotrigine tablets as a generic. Under the facts averred in the Complaint—which must be taken as true for purposes of deciding GSK's motion—"GSK has offered customers—including pharmacies, large pharmacy chains, group purchasing organizations, and long-term care facilities—proposals by which customers will commit to purchase GSK's lamotrigine products to be sold as generic equivalent products to consumers." Compl. ¶ 25. One such proposal required participating retail pharmacies to treat Lamictal® tablets "as the generic"—GSK's own words—during the term of the agreement. *Id.* Because GSK itself conceded in these proposals that the lamotrigine it sought to sell would be sold "as the generic," this Court should ignore GSK's attempts to philosophize that the true meaning of "generic" is somehow unclear.

The GSK proposal calls for customers to dispense products using what is known as a "DAW5" code, "which is used by managed care organizations and state Medicaid programs to signify that a branded product is being dispensed as a generic." Compl. ¶ 26. For example, the West Virginia Department of Health and Human Services states that use of DAW5 means "[p]harmacy uses this brand *as its generic* but realizes it will be paid at the generic rate." *Id.* (emphasis added). Similarly, the Medicaid Provider Services for the State of Colorado recognize that a DAW5 code signifies "substitution allowed – brand as generic." *Id.* Far from being irrelevant, as GSK contends, these facts establish that GSK did exactly what the parties intended the License Agreement to prohibit. That GSK's proposals tied benefits to customers to the dispensing of Lamictal® lamotrigine tablets in situations specifically calling for the generic

equivalent through use of DAW5 codes, demonstrates that GSK was marketing its Lamictal® tablets as a generic.

The ruse that GSK came up with to market its Lamictal® tablets as a generic cannot legitimately be characterized as a mere attempt to make Lamictal® tablets price competitive with Teva's generic tablets, as GSK now contends. GSK's Br. (Docket Item 27) at 10. There is no dispute that GSK could simply have sold Lamictal® at significantly lower prices in order to compete with Teva's generic tablets. But GSK did not take this approach, presumably because it would have been transparent to Teva and would not have interfered with Teva's launch to the extent GSK desired. Instead, GSK employed a more opaque approach to try to undermine Teva, which aimed not at price reduction, but at blocking Teva's market penetration and consumers' ability to substitute generic lamotrigine for Lamictal®. GSK's approach was to do precisely what the License Agreement prohibits, *i.e.*, to market a lamotrigine product—in this case Lamictal® tablets—as a generic during the limited duration of the exclusivity it granted Teva.

In any event, GSK's argument is premised on facts not before this Court—namely, that it was discounting Lamictal® in response to Teva's launch—which will be disputed. Teva intends to show that GSK's scheme was even more nefarious: rather than simply provide discounts on Lamictal®, GSK's program sought to require participants to accept GSK's higher-priced Lamictal® rather than Teva's lower-priced substitute. In return for this, GSK would provide a variety of other inducements to customers intended to make them whole to the extent that GSK was able to preclude Teva's generic lamotrigine from gaining acceptance. The premise of GSK's argument—that it was simply engaged in innocent discounting—is a disputed fact that is not properly before this Court.

D. Even if GSK's Interpretation of the License Agreement Somehow Made Sense, Then the "Generic Equivalent" Definition on Which GSK Relies Would Still Be Ambiguous and Preclude Judgment on the Pleadings.

Even if the License Agreement could somehow make sense under GSK's interpretation, it would still not be appropriate for this Court to grant GSK's motion. All that GSK would have established is that the "Generic Equivalent" definition on which it relies is ambiguous. The ambiguity would exist because Teva's interpretation of the definition—*i.e.*, that it precludes GSK from selling into the generic market but does not otherwise restrict GSK's sales of Lamictal®—is at least equally reasonable as GSK's interpretation that the final sentence negates the entire "Generic Equivalent" definition.[12] In addition, Teva intends to demonstrate that the final sentence of the definition of "Generic Equivalent" was drafted by GSK. Under the rule of *contra proferentem*, the ambiguity in this sentence will have to be construed against GSK and in favor of Teva.[13]

Where contract provisions are ambiguous, there exists a fact dispute that cannot be resolved based solely on the pleadings. *See Emerson Radio Corp. v. Orion Sales, Inc.*, 253 F.3d 159, 163 (3d Cir. 2001) (It is "hornbook law that if the relevant terms in a contract are ambiguous, the issue must go to a jury"); *Fox Cable Networks, Inc. v. Goen Techs. Corp.*, No. 05-CV-3487 (WJM), 2008 WL 2165179, *3 (D.N.J. May 20, 2008) ("When written contract provisions are ambiguous or incomplete, interpretation of the contract is a task for the jury."). Moreover, the parties would be entitled to develop the record and introduce parol evidence to

[12] *See Madison Construc. Co. v. Harleysville Mut. Ins. Co.*, 557 Pa. 595, 735 A.2d 100, 106 (Pa. 1999) ("Contractual terms are ambiguous if they are subject to more than one reasonable interpretation when applied to a particular set of facts.").

[13] *Rusiski v. Pribonic*, 511 Pa. 383, 515 A.2d 507 (1986); *see also Kiewit Eastern Co., Inc. v. L & R Const. Co., Inc.*, 44 F.3d 1194, 1203 (3d Cir. 1995) ("[I]f an agreement is ambiguous, it is to be construed 'most strongly' against the party who drafted it.") (quoting *Pittsburgh Steel Co. v. Patterson-Emerson-Comstock, Inc.*, 404 Pa. 53, 60, 171 A.2d 185, 189 (1961)).

explain the meaning of ambiguous contract provisions, and thus the parties will require discovery to address the ambiguous language of the final sentence of the "Generic Equivalent" definition. GSK's motion for judgment on the pleadings is thus, at best, entirely premature. *See Ford Motor Co. v. Edgewood Props.*, Nos. 06-1278, 06-4266, 2008 WL 4559770, *14 (D.N.J. Oct. 18, 2008) (denying motion to dismiss breach-of-contract claim where movant's proposed construction was only a "plausible" interpretation of an ambiguous term).

CONCLUSION

For the foregoing reasons, GSK's motion for judgment on the pleadings should be denied in all respects.

LITE DEPALMA GREENBERG & RIVAS, LLC

Dated: December 15, 2008

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